Scientific Data in Regulatory Decision-Making

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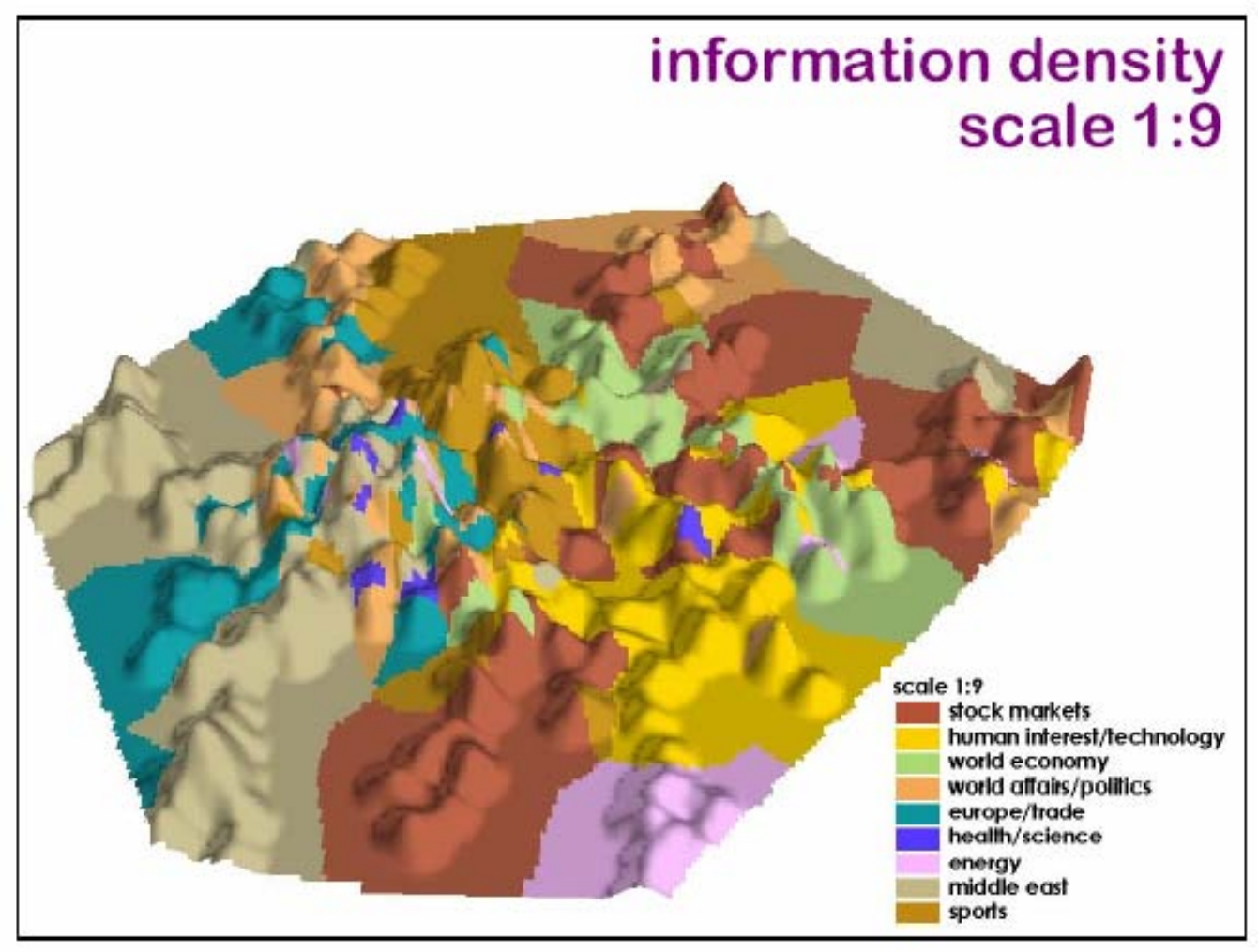
Introduction

- Description of the OAQPS air toxics universe as an n-dimensional space
- The OAQPS tiering strategy, i.e., how we cope
- Ways in which better-organized toxicological information could help us

The Air Toxics Universe



Association of American Geographers (2002)

OAQPS Air Toxics Universe: Width

- 174 Source categories & 96 NESHAPS
- National Air Toxics Assessment activities
  - Monitoring
  - Inventory
  - Assisting communities with local risk assessments
  - National-scale assessment
- 1-Time “boutique” assessments (e.g., mercury study, power generation assessment)
- Adding and removing HAPs

OAQPS Air Toxics Universe: Length

- Every assessment includes both dose-response and exposure analyses
  - Exposure generally takes most resources
    - Tailored to situations
  - Dose-response often gets overlooked
    - Only 2 toxicologist on board, and we pay a lot of attention to exposure
    - Program office mindset tends to treat dose-response values as physical constants

OAQPS Air Toxics Universe: Depth

- Focusing on DR, we need to concern ourselves with 188 HAPs
  - Really many more than this, because:
    - 20 are “category” HAPs (e.g., POM, glycol ethers) whose members vary widely in toxicity
    - Listing assessments (i.e., substances not on list that should be)
  - Delisting assessments (i.e., data needed on least toxic HAPs)

OAQPS Air Toxics Universe: Dimensions 4-6

- For these 188 HAPs, we must concern ourselves with
  - Inhalation and multipathway exposures
  - Chronic and acute time scales
  - Human and ecological receptors

How We Cope: Tiering

Complete study-specific data, no assumptions; higher cost, lower uncertainty

Add quantitative uncertainty/variability analysis

More refined exposure assessment

More refined dispersion & exposure modeling

Simple dispersion model

Lookup Table

No data, all assumptions; lower cost, high uncertainty

How We Cope: Tiering

- Assessment in multiple iterations
  - Initial screen – Toxicity-weighted scoring
  - Tier 1 – Simple, conservative screens focus assessment on important stressors and sources
  - Tier 2 – More complex models, real receptors
  - Tier 3 – Best available analysis for risk drivers

Benefits and Limitations of Tiering

- Lower-tier assessments generally support
  - Decisions not to regulate
  - Focusing resources on a small number of stressors and sources for next iteration
- They generally do not support
  - Decisions to reduce emissions
    - These usually require best available science in analysis of both exposure and dose-response

Dose-Response and Tiering

- Dose-response assessments generic until Tier 3
  - E.g., IRIS, ATSDR, NAC/AEGL, etc.
  - 242 HAPs with chronic assessments
  - 134 with 1 or more acute assessments
- For Tier 3, only newest and best existing assessments suffice
  - If newer data are available, OAQPS must consider them to be credible
  - Also, many HAPs lack acute assessments
    - Need a data-driven process to distinguish important from trivial for these

OAQPS's Toxicological Data Needs

- We can get by with existing dose-response values for many risk assessments
- But not all; We need best possible dose-response values for the following determinations:
  - Supporting requirements for emission reduction
  - Decisions to remove a HAP
  - Decisions to list a HAP
  - Prioritizing OAQPS's research needs
- Better-organized toxicological information would provide important support to these activities

Emission Reduction Rules

- Plywood MACT
  - IRIS formaldehyde URE obsolete
  - Risk estimates based on PBPK model developed by CIIT
- Residual risk rules (20 underway)
  - Standard DR sources used for tiers 1 and 2
  - Tier 3 will often require update of old dose-response values

Removing a HAP

- CAA test: must demonstrate absence of risk
- Methanol
  - Decision delayed pending evaluation of recent data
    - Petition eventually denied
    - Ensuing suit by petitioner
- EGBE
  - ORD conducted extensive review of data
    - Developed analysis of cancer and noncancer effects
    - EPA has proposed delisting
- Better organization of toxicological data would have expedited these and other delisting decisions

Listing a HAP

- CAA test: must demonstrate presence of risk
- H_2S
  - Chronic and acute dose-response assessments obsolete
    - EPA co-sponsored symposium to discuss current understanding
    - ORD did chronic; NAC/AEGL did acute
    - OAQPS now evaluating exposures
  - Better-organized data would have been useful to all parties

Prioritizing Research Needs

- CAA universe of HAPs includes hundreds of substances
  - IRIS assesses about ten per year for all programs
  - OAQPS needs to keep track of which HAPs have acquired enough data to support a new assessment
- Better-organized data would help us become more methodical about these decisions

Summary

- Activities that would benefit from some kind of toxicological data system:
  - Supporting residual risk determinations to reduce emissions (as opposed to no-action decisions)
  - Supporting listing and delisting decisions
  - Selection of IRIS starts